BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2013-0075; FRL-9378-8]

FIFRA Scientific Advisory Panel; Notice of Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: There will be a 4-day meeting of the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (FIFRA SAP) to consider and review the Endocrine Disruptor Screening Program (EDSP) Tier 1 Screening Assays and Battery Performance.

DATES: The meeting will be held on May 21 - 24, 2013, from approximately 9 a.m. to 5 p.m.

Comments. The Agency encourages that written comments be submitted by May 7, 2013 and requests for oral comments be submitted by May 14, 2013. However, written comments and requests to make oral comments may be submitted until the date of the meeting, but anyone submitting written comments after May 7, 2013 should contact the Designated Federal Official (DFO) listed under **FOR FURTHER INFORMATION CONTACT.** For additional instructions, see Unit I.C. of the **SUPPLEMENTARY INFORMATION**.

Nominations. Nominations of candidates to serve as ad hoc members of FIFRA SAP for this meeting should be provided on or before [*insert date 14* days *from date of publication in the* **Federal Register**].

Webcast. This meeting may be webcast. Please refer to the FIFRA SAP's website, *http://www.epa.gov/scipoly/sap* for information on how to access the webcast. Please note that the webcast is a supplementary public process provided only for convenience. If difficulties arise resulting in webcasting outages, the meeting will continue as planned.

Special accommodations. For information on access or services for individuals with disabilities, and to request accommodation of a disability, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** at least 10 days prior to the meeting to give EPA as much time as possible to process your request.

ADDRESSES: The meeting will be held at the Environmental Protection Agency, Conference Center, Lobby Level, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA 22202.

Comments. Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2013-0075, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

• *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

If your comments contain any information that you consider to be CBI or otherwise protected, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** to obtain special instructions before submitting your comments.

Nominations, requests to present oral comments, and requests for special accommodations. Submit nominations to serve as ad hoc members of FIFRA SAP, requests for special seating accommodations, or requests to present oral comments to the DFO listed under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Fred Jenkins Jr., DFO, Office of Science Coordination and Policy (7201M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-3327; fax number: (202) 564-8382; email address*: jenkins.fred@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be of interest to persons who are or may be required to conduct testing of chemical substances under the Federal Food, Drug, and Cosmetic Act (FFDCA) and FIFRA. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. What Should I Consider as I Prepare My Comments for EPA?

When submitting comments, remember to:

1. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

2. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

3. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

4. Describe any assumptions and provide any technical information and/or data that you used.

5. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

6. Provide specific examples to illustrate your concerns and suggest alternatives.

7. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

8. Make sure to submit your comments by the comment period deadline identified.

C. How May I Participate in this Meeting?

You may participate in this meeting by following the instructions in this unit. To ensure proper receipt by EPA, it is imperative that you identify docket ID number EPA-HQ-OPP-2013-0075 in the subject line on the first page of your request.

1. *Written comments*. The Agency encourages that written comments be submitted, using the instructions in **ADDRESSES**, no later than May 7, 2013, to provide FIFRA SAP the time necessary to consider and review the written comments. Written comments are accepted until the date of the meeting, but anyone submitting written comments after May 7, 2013 should contact the DFO listed under **FOR FURTHER INFORMATION CONTACT.** Anyone submitting written comments at the meeting should bring 25 copies for distribution to FIFRA SAP.

2. *Oral comments*. The Agency encourages that each individual or group wishing to make brief oral comments to FIFRA SAP submit their request to the DFO listed under **FOR FURTHER INFORMATION CONTACT** no later than May 14, 2013, in order to be included on the meeting agenda. Requests to present oral comments will be accepted until the date of the meeting and, to the extent that time permits, the Chair of FIFRA SAP may permit the presentation of oral comments at the meeting by interested persons who have not previously requested time. The request should identify the name of the individual making the presentation, the organization (if any) the individual will represent, and any requirements for audiovisual equipment (e.g., overhead projector, 35 mm projector). Oral comments before FIFRA SAP are limited to approximately 5 minutes unless prior arrangements have been made. In addition, each speaker should bring 25 copies of his or her comments and presentation slides for distribution to the FIFRA SAP at the meeting.

3. *Seating at the meeting*. Seating at the meeting will be open and on a first-come basis.

4. *Request for nominations to serve as ad hoc members of FIFRA SAP for this meeting*. As part of a broader process for developing a pool of candidates for each meeting, FIFRA SAP staff routinely solicits the stakeholder community for nominations of prospective candidates for service as ad hoc members of FIFRA SAP. Any interested person or organization may nominate qualified individuals to be considered as prospective candidates for a specific meeting. Individuals nominated for this meeting should have expertise in one or more of the following areas: Regulatory toxicology/risk assessment, ecotoxicology (fish and amphibian toxicology), comparative endocrinology, reproductive physiology, developmental biology/toxicology, thyroid physiology, *in vitro* models, toxicological pathology, amphibian histopathology, morphometrics, quantitative ecology/biostatistics, and systems biology. Nominees should be scientists who have sufficient professional qualifications, including training and experience, to be capable of providing expert comments on the scientific issues for this meeting. Nominees should be identified by name, occupation, position, address, and telephone number. Nominations should be provided to the DFO listed under **FOR FURTHER INFORMATION CONTACT** on or before [*insert date 14 days from date of publication in the* **Federal Register**]. The Agency will consider all nominations of prospective candidates for this meeting that are received on or before this date. However, final selection of ad hoc members for this meeting is a discretionary function of the Agency.

The selection of scientists to serve on FIFRA SAP is based on the function of the panel and the expertise needed to address the Agency's charge to the panel. No interested scientists shall be ineligible to serve by reason of their membership on any other advisory committee to a Federal department or agency or their employment by a Federal

department or agency except the EPA. Other factors considered during the selection process include availability of the potential panel member to fully participate in the panel's reviews, absence of any conflicts of interest or appearance of lack of impartiality, independence with respect to the matters under review, and lack of bias. Although financial conflicts of interest, the appearance of lack of impartiality, lack of independence, and bias may result in disqualification, the absence of such concerns does not assure that a candidate will be selected to serve on FIFRA SAP. Numerous qualified candidates are identified for each panel. Therefore, selection decisions involve carefully weighing a number of factors including the candidates' areas of expertise and professional qualifications and achieving an overall balance of different scientific perspectives on the panel. In order to have the collective breadth of experience needed to address the Agency's charge for this meeting, the Agency anticipates selecting approximately 10 ad hoc scientists.

FIFRA SAP members are subject to the provisions of 5 CFR part 2634, Executive Branch Financial Disclosure, as supplemented by the EPA in 5 CFR part 6401. In anticipation of this requirement, prospective candidates for service on the FIFRA SAP will be asked to submit confidential financial information which shall fully disclose, among other financial interests, the candidate's employment, stocks and bonds, and where applicable, sources of research support. The EPA will evaluate the candidates financial disclosure form to assess whether there are financial conflicts of interest, appearance of a lack of impartiality or any prior involvement with the development of the documents under consideration (including previous scientific peer review) before the candidate is considered further for service on FIFRA SAP. Those who are selected from the pool of

prospective candidates will be asked to attend the public meetings and to participate in the discussion of key issues and assumptions at these meetings. In addition, they will be asked to review and to help finalize the meeting minutes. The list of FIFRA SAP members participating at this meeting will be posted on the FIFRA SAP website at *http://www.epa.gov/scipoly/sap* or may be obtained from the OPP Docket or at *http://www.regulations.gov*.

II. Background

A. Purpose of FIFRA SAP

FIFRA SAP serves as the primary scientific peer review mechanism of EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) and is structured to provide scientific advice, information and recommendations to the EPA Administrator on pesticides and pesticide-related issues as to the impact of regulatory actions on health and the environment. FIFRA SAP is a Federal advisory committee established in 1975 under FIFRA that operates in accordance with requirements of the Federal Advisory Committee Act. FIFRA SAP is composed of a permanent panel consisting of seven members who are appointed by the EPA Administrator from nominees provided by the National Institutes of Health and the National Science Foundation. FIFRA established a Science Review Board consisting of at least 60 scientists who are available to the SAP on an ad hoc basis to assist in reviews conducted by the SAP. As a peer review mechanism, FIFRA SAP provides comments, evaluations and recommendations to improve the effectiveness and quality of analyses made by Agency scientists. Members of FIFRA SAP are scientists who have sufficient professional qualifications, including training and experience, to provide expert advice and recommendation to the Agency.

B. Public Meeting

Under the Federal Food, Drug, and Cosmetic Act (FFDCA), section 408(p) and the Safe Drinking Water Act (SDWA), section 1457, the EPA is required to screen all pesticide chemicals (active and inert ingredients) and those drinking water contaminants to which a "substantial population" is exposed for the potential to interact with the endocrine system. As recommended by a Federal Advisory Committee, (Endocrine Disruptor Screening and Testing Advisory Committee, EDSTAC), the EPA Endocrine Disruptor Screening Program (EDSP) established a two tiered screening and testing program to address the potential of chemicals to perturb the estrogen, androgen or thyroid (E,A or T) systems and elicit adverse human and ecological health outcomes. In 1999, following the EDSTAC recommendations, a joint subcommittee of the Agency's Science Advisory Board (SAB) and FIFRA SAP recommended to the Agency, after review of the initial set of Tier 1 data, to subject that data to external scientific peer review for consideration to further optimize the Tier 1 screening battery.

Tier 1 screening was recommended to include a diverse yet complementary suite of *in vitro* and *in vivo* assays covering multiple hormonal modes of action (MoA) across various taxa. To maximize sensitivity and reliability (i.e., minimizing false negatives) for determining the potential of a chemical to interact with E, A, or T, the suite of assays was to be conducted as a battery. If the results of the Tier 1 battery indicated the potential for a chemical to interact with the endocrine system as determined through a weight of evidence (WoE) analysis, various Tier 2 tests were to be considered for determining dose-response relationships and any potential adverse effects for risk assessment.

The EDSP is mandated under FFDCA to use "validated" assays to screen for endocrine disrupting chemicals. Validation principles established by the Organization for Economic Co-Operation and Development (OECD) and Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) were followed to develop, standardize, and validate many of the initially proposed Tier 1 *in vitro* and *in vivo* screening assays as well as more novel screening assays that emerged after the EDSTAC final report in 1998. Subsequent to the validation process, an independent peer review of individual Tier 1 screening assays was conducted. Based on results of the validation process, comments from peer review, and recommendations from EDSTAC, the EDSP proposed a battery of screening assays that was founded on the strengths of one or more assays complimenting the limitations of other assays in the battery. Moreover, it was expected that the result(s) of each assay would not be considered in isolation but be inclusive of the results of all assays in the battery to support a WoE analysis. The FIFRA SAP reviewed the proposed Tier 1 screening battery and recommended a battery of 11 assays to EPA which the Panel indicated *"…as an appropriate starting point to detect endocrine disrupting chemicals based on the current state of the science."* In addition, however, the SAP also expected the Agency to continue *"…to develop, refine, and review the battery."* Notably, this latter statement concurs with a recommendation from the initial joint SAB/SAP who indicated EPA should review the initial data *"…with an eye towards revising the process and eliminating those methods that don't work."*

This FIFRA SAP review will be focused on a subset of the initial Tier 1 screening data received by the Agency in response to test orders issued for the first list of chemicals in 2009. The SAP review will involve the performance of the 11 Tier 1 screening assays

and performance of the assays as a battery that was designed to detect the potential of a test chemical to interact with the E, A or T hormonal pathways. The SAP will be asked to comment on factors that may impact interpretation of the assay/battery results (e.g., variability) as well as suggestions for increasing the efficiency of the Tier 1 screening approach. To illustrate assay/battery performances, case examples of Tier 1 data from the initial list of chemicals will be used. It should be noted that there will be a separate SAP meeting scheduled in the summer of 2013 to discuss the decision logic in a WoE approach to identify candidate chemicals for Tier 2 testing using EDSP Tier 1 screening results, other scientifically relevant information (OSRI), and health and ecological effects data from 40 CFR part 158 studies.

C. FIFRA SAP Documents and Meeting Minutes

EPA's background paper, related supporting materials, charge/questions to FIFRA SAP, FIFRA SAP composition (i.e., members and ad hoc members for this meeting), and the meeting agenda will be available by approximately early May 2013. In addition, the Agency may provide additional background documents as the materials become available. You may obtain electronic copies of these documents, and certain other related documents that might be available electronically, at *http://www.regulations.gov* and the FIFRA SAP homepage at *http://www.epa.gov/scipoly/sap*.

FIFRA SAP will prepare meeting minutes summarizing its recommendations to the Agency approximately 90 days after the meeting. The meeting minutes will be posted on the FIFRA SAP website or may be obtained from the OPP Docket or at *http://www.regulations.gov*.

List of Subjects

Environmental protection, Pesticides and pests, and Endocrine disruptors.

Dated: February 13, 2013.

Steven M. Knott, Acting

Director, Office of Science Coordination and Policy.

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